

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Paul E. Plunkett	Sitting Judge If Other than Assigned Judge	
CASE NUMBER	98 C 4293	DATE	12/3/2003
CASE TITLE	Warner Lambert Co. vs. Apotex Corp., et al		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

- (1) ☐ Filed motion of [use listing in "Motion" box above.]
- (2) ☐ Brief in support of motion due _____.
- (3) ☐ Answer brief to motion due _____. Reply to answer brief due _____.
- (4) ☐ Ruling/Hearing on _____ set for _____ at _____.
- (5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.
- (6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.
- (7) ☐ Trial[set for/re-set for] on _____ at _____.
- (8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.
- (9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).
- (10) ☒ [Other docket entry] ENTER MEMORANDUM OPINION AND ORDER: the Court accepts the magistrate judge's Report and Recommendation and denies TorPharm's motion for attorneys' fees under 35 U.S.C. Section 285 and Rule 11. We award TorPharm costs in the amount of \$20,876.53.

- (11) ☒ [For further detail see order attached to the original minute order.]

No notices required, advised in open court.	U.S. DISTRICT COURT CLERK 03 DEC - 3 PM 3:05 01 DEC 03 11:41 Date time received in central Clerk's Office	number of notices	Document Number 138
No notices required.		DEC 04 2003 date docketed	
Notices mailed by judge's staff.		<i>[Signature]</i> docketing deputy initials	
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**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

DOCKETED

DEC 04 2003

WARNER-LAMBERT COMPANY,

Plaintiff,

v.

**APOTEX CORP., APOTEX, INC. and
TORPHARM, INC.,**

Defendants.

No. 98 C 4293

Paul E. Plunkett, Senior Judge

MEMORANDUM OPINION AND ORDER

This matter is before us on defendants' ("TorPharm") objections to Magistrate Judge Keys' Report and Recommendation ("R&R") in which Magistrate Judge Keys recommended that we deny TorPharm's motion for attorneys' fees but award costs in the amount of \$20,876.53. For the reasons set forth below, we accept the magistrate judge's R&R and deny TorPharm's motion for attorneys' fees but award TorPharm costs in the amount of \$20,876.53.¹

¹ No objections were filed to Magistrate Judge Keys' recommendation that costs in the amount of \$20,876.53 be awarded to TorPharm.

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I. Background²

Warner-Lambert, plaintiff, holds various patents involving gabapentin, an amino acid compound proven safe and effective in the treatment of epilepsy. At issue in this case are two of those patents: U.S. Patent No. 4,894,476 (the '476 patent) and U.S. Patent No. 5,084,479 (the '479 patent). The '476 patent discloses gabapentin monohydrate, a form of gabapentin containing water, and a process for producing gabapentin. The '476 patent expires in 2008. The '479 patent discloses the invention of "novel uses of known cyclic amino acids [including gabapentin] for treating neurodegenerative disorders, perinatal asphyxia, *status epilepticus*, Alzheimer's, Huntington's, Parkinson's, and Amyotrophic Lateral Sclerosis." U.S. Patent No. 5,084,479 abstract. The '479 patent expires in 2010.

Warner-Lambert also holds two expired patents relating to gabapentin. One patent discloses the compounds used in the '479 patent (including gabapentin in its water-free, or anhydrous, form) and the other patent discloses a method of using gabapentin (and certain other compounds) to treat certain forms of epilepsy and other disorders. Because these two patents have expired, both the compounds claimed in the one patent (anhydrous gabapentin) and the method of using those compounds claimed in the other patent (treatment of epilepsy) are now in the public domain.

² A more comprehensive discussion of the background of this case can be found in various court opinions. See *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003); *Warner-Lambert Co. v. Apotex Corp.*, 2001 WL 1104618 (N.D. Ill. Sept. 14, 2001); *Warner-Lambert Co. v. Apotex Corp.*, 2001 WL 735024 (N.D. Ill. June 28, 2001); *Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293 (Order dated March 2, 2001); *Warner-Lambert Co. v. Apotex Corp.*, 1999 WL 259946 (N.D. Ill. Apr. 8, 1999).

In addition, Warner-Lambert holds an approved New Drug Application (NDA) issued in 1993 by the United States Food and Drug Administration (FDA).³ The NDA allows Warner-Lambert to market gabapentin for use in "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." Warner-Lambert markets the drug under the trade name Neurontin®. The FDA has not approved gabapentin for any other uses.

In April 1998, TorPharm filed an Abbreviated New Drug Application (ANDA) with the FDA.⁴ In the ANDA, TorPharm sought permission to market a generic version of gabapentin "for adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." Pursuant to statutory requirements, when TorPharm filed its ANDA it notified Warner-Lambert (through a "paragraph IV certification") that its generic gabapentin, to be used in the treatment of epilepsy, would infringe neither the '476 nor the '479 patent. Warner-Lambert disagreed and sued TorPharm for infringement of both patents under 35 U.S.C. § 271(e)(2).⁵ Because Warner-Lambert sued within forty-five days of receiving the paragraph IV certification, the FDA by law was prevented from approving the ANDA for a period of thirty months or until a court decided the issues raised in the suit. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The approval of TorPharm's ANDA, and TorPharm's ability to market and sell the generic drug, was thus delayed pending the outcome of this case.

³ Before a drug manufacturer can market a new drug, it must obtain permission from the FDA. The approval process requires the submission of an NDA, which includes drug safety information, efficacy information and composition data. 21 U.S.C. §§ 355 (a) & (b).

⁴ A generic drug manufacturer files an ANDA with the FDA when seeking permission to market the generic version of a drug covered by an NDA. 21 U.S.C. § 355(j).

⁵ This section provides in part that it is an act of infringement to file an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent"

TorPharm was successful in defending against both infringement claims. We granted TorPharm's motion for summary judgment on the '476 patent infringement claim in June 2001 and a few months later we granted TorPharm's motion for summary judgment on the '479 patent infringement claim. Warner-Lambert appealed the decision on the '479 patent, and in January 2003, the Federal Circuit affirmed.⁶ TorPharm now seeks attorneys' fees pursuant to 35 U.S.C. § 285 and Rule 11 of the Federal Rules of Civil Procedure (Rule 11), essentially arguing the same position under both measures: Warner-Lambert pursued its infringement claims even though it knew the claims had no basis in law or fact. According to TorPharm, Warner-Lambert's litigation of the claims was done solely to delay FDA approval of TorPharm's generic gabapentin product, thereby extending Warner-Lambert's lucrative gabapentin monopoly. TorPharm seeks to recover \$726,932.38 in fees and expenses and \$22,260.01 in costs.

II. Discussion

Legal Standard

A decision to award attorneys' fees under 35 U.S.C. § 285 (section 285) is a two-step process. First, a prevailing party must prove by clear and convincing evidence that the case is "exceptional." Second, if a court finds the case exceptional, then it must determine whether the award of attorneys' fees is appropriate. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1327-28 (Fed. Cir. 2003). Cases that are exceptional are those involving "inequitable conduct . . . ; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." *Id.* at 1329 (quoting *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370,

⁶ See opinions related to these decision listed at *supra* n.2.

1378 (Fed. Cir. 2001)). The award of attorneys' fees under section 285 is not meant to be a frequent occurrence; it is limited to cases where it is necessary to prevent a "gross injustice" to the accused infringer. *Id.* (internal citations omitted).

TorPharm has invoked the "frivolous suit" category of an exceptional case. A frivolous infringement suit is one that the patentee either knew, or on reasonable investigation should have known, was baseless. *Haynes Int'l Co. v. Jessop Steel Co.*, 8 F.3d 1573, 1579 (Fed. Cir. 1994).

In the alternative, TorPharm seeks attorneys' fees as sanctions under Rule 11. Summarized very briefly, Rule 11 provides for sanctions when a party knowingly presents a pleading, written motion or other paper to the court that is used for an improper purpose or has no basis in law or fact. Fed. R. Civ. P. 11.

We referred this matter to Magistrate Judge Keys, who determined that the case was not "exceptional" under 35 U.S.C. § 285 nor did it warrant the award of attorneys' fees as sanctions under Rule 11. The magistrate judge did determine that TorPharm was entitled to recover \$20,876.53 in costs. TorPharm has filed objections to the magistrate judge's R&R and Warner-Lambert has responded to those objections.

We review *de novo* portions of the magistrate judge's R&R to which specific written objections have been made. Fed. R. Civ. P. 72(b); *Goffman v. Gross*, 59 F.3d 668, 671 (7th Cir. 1995). We can "accept, reject or modify the recommended decision" Fed. R. Civ. P. 72(b).

TorPharm's Objections to the R&R

A. The '476 Patent

1. The Magistrate Judge Ignored Evidence of Warner-Lambert's Pre-Suit Knowledge That Gabapentin Anhydrous Was Made by Teva in Israel Only.

In essence, the infringement claim on the '476 patent was this: the '476 patent covered gabapentin monohydrate, a form of gabapentin containing water. TorPharm's ANDA covered gabapentin anhydrate, a waterless form of gabapentin. Gabapentin anhydrate is covered by an expired Warner-Lambert patent, so Warner-Lambert cannot prevent others from producing this substance. Warner-Lambert maintained, however, that the infringement of the '476 patent came from using the monohydrate in the United States at some point during the process of manufacturing gabapentin anhydrate.

TorPharm argues that before the suit was filed, Warner-Lambert knew that the anhydrous gabapentin was manufactured for TorPharm in Israel by a company called Teva, and that even if Teva used the monohydrate during an intermediate step in its manufacturing process, it did not infringe Warner-Lambert's patent because the use was in Israel. *See* 35 U.S.C. § 271(a) (limiting infringement claims to activities in the United States). Thus, Warner-Lambert knew that its '476 patent infringement claim was baseless, rendering this case exceptional under 35 U.S.C. § 285 and/or ripe for sanctions under Rule 11. The magistrate judge, says TorPharm, ignored the evidence on this point.

In support of its argument, TorPharm directs us to testimony by John Joubran, Warner-Lambert's senior director of sourcing procurement, where Joubran said that in 1995 he learned of several companies that were manufacturing gabapentin, including Teva in Israel. (Def.'s Ex. G, Tab

1 at 10.) TorPharm also directs us to two 1998 Warner-Lambert e-mails created before the suit was filed. The e-mails state that, because of reduced labor costs, generic manufacturers, like Teva in Israel, produce gabapentin at a cost lower than Warner-Lambert's. Joubran is identified as the person with the relevant cost-analysis information. (*Id.* Tabs 4, 5.) TorPharm asserts that this clearly shows Warner-Lambert knew before it filed its patent infringement claim that Teva manufactured gabapentin solely in Israel, and, therefore, TorPharm was not infringing the '476 patent.

We disagree that this constitutes clear and convincing evidence that Warner-Lambert knew its patent infringement claim was baseless before it filed suit. Warner-Lambert maintains that it had no actual knowledge of Teva's manufacturing process. Joubran's testimony indicates that neither he nor, to his knowledge, anyone at Warner-Lambert received "any documents relating to [Teva's] gabapentin products, or the processes that [were used] to make it." (Def.'s Ex. G. Tab 1 at 14.) Although Warner-Lambert tested Teva's product, once it determined that the product did not meet its specifications, communications with Teva ceased. (*Id.* at 18.) In addition, when communicating with Teva initially about obtaining the gabapentin sample, Joubran spoke with a Teva representative in the United States, which could suggest close ties between Teva/Israel and U.S. facilities.⁷ (*Id.* at 20.) Regarding the 1998 e-mails and their suggestion Joubran had specific knowledge about Teva to complete a cost analysis, Joubran stated that he "guessed" the relevant information to use in his analysis and based his assumptions on Warner-Lambert's own production process. (*Id.* at 30, 33-34.)

The evidence shows Warner-Lambert knew that Teva, a company based in Israel, manufactured gabapentin, but given the ease with which manufacturing processes and products cross borders, we do not agree that the evidence shows it is highly probable that Warner-Lambert knew

⁷ In fact, Teva has subsidiaries in the U.S.

before it filed suit that Teva's entire gabapentin manufacturing process was conducted entirely in Israel. *See Gonten v. Research Sys. Corp.*, 739 F.2d 1264, 1268 (7th Cir. 1984) (according to the Supreme Court, clear and convincing evidence is evidence that shows something is highly probable). TorPharm has not demonstrated that Warner-Lambert initiated a frivolous suit with respect to this claim. *See Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1364 (Fed. Cir. 2000) (it was reasonable for plaintiff to file suit and engage in discovery when, prior to filing suit, plaintiff had "neither evidence of infringement nor non-infringement").

2. The Magistrate Judge Improperly Concluded That Warner-Lambert Could Continue Its Suit for Two Years Even Though There Was Overwhelming Evidence of Non-Infringement.

TorPharm claims that the documents produced at the beginning of the discovery process constitute a "virtual tidal wave of noninfringing evidence" and that, when faced with this evidence, Warner-Lambert could not have maintained its suit in good faith. Maintaining a frivolous suit can lead to the award of attorneys' fees under 35 U.S.C. § 285, *see Haynes*, 8 F.3d at 1580, but we do not agree that TorPharm's evidence clearly demonstrates that Warner-Lambert knew during the course of discovery that its claim could not be sustained.

TorPharm emphasizes the ANDA itself and the information contained therein as evidence that its gabapentin could not infringe the '476 patent. (Def.'s Ex. G, Tabs 7, 8, 9.) But the ANDA provides little in the way of the specific information that Warner-Lambert sought – whether Teva used the monohydrate in the United States during the course of its anhydrous gabapentin manufacturing process. Although the ANDA indicates that the drug manufacturer is located in Beer Sheva, Israel, it did not explain the manufacturing process in a way that addressed Warner-Lambert's

concerns. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1250 (Fed. Cir. 2000) (focusing on the information provided in the ANDA and whether it directly addressed the issue of infringement). Warner-Lambert considered this missing information significant because its '476 patent disclosed a manufacturing process for anhydrous gabapentin that uses the monohydrous form. According to Warner-Lambert, generic manufacturers may use this method in their production of the anhydrate because it provides efficiency advantages over producing anhydrous gabapentin through a non-monohydrate process.

The ANDA and other information provided by TorPharm in the early stages of discovery were not responsive to Warner-Lambert's concern. TorPharm was not involved in Teva's manufacturing process; TorPharm was Teva's customer and played no role in directing its activities or helping it develop the capability to make the generic product. (Pl.'s Ex. 10 at 15-16.) Therefore, TorPharm could not speak to Teva's manufacturing process and relied on Teva's own representations regarding the manufacture of generic gabapentin. The document that apparently would have answered Warner-Lambert's questions about the manufacturing process was not, according to TorPharm, in TorPharm's possession nor was there any other document in TorPharm's possession that would have provided the same information. (*Id.* at 13-16.) Warner-Lambert did attempt to get the information it needed from Teva in Israel,⁸ but its inquiries did not yield satisfactory results.

The Federal Rules of Civil Procedure contemplate a liberal discovery process, *see Katz v. Batavia Marine & Sporting Supplies, Inc.*, 984 F.2d 422, 424 (Fed. Cir. 1993), and Warner-Lambert had the right to conduct a fair and reasonable investigation of its claims. The purpose of creating

⁸ Warner-Lambert was involved in a parallel litigation involving Teva's manufacture of gabapentin for a different generic drug company in the United States. *See Warner-Lambert v. Purepac*, Nos. 98 C 2749 & 99 C 5948 (D.N.J.). During that litigation, Warner-Lambert sought information from Teva in Israel.

a cause of action under 35 U.S.C. § 271(e)(2)(A) from the filing of an ANDA is to allow courts to promptly resolve disputes involving a generic drug and the question of whether it infringes a patented product, and the thirty-month stay creates an adequate window of time to litigate that question. *See Bayer AG*, 212 F.3d at 1249; *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001) (internal citations to Congressional Record omitted). Pursuant to our inherent authority to manage our cases, we allowed Warner-Lambert time to get the information it needed to maintain its infringement claim.⁹ (Pl.'s Ex. 10 at 50-57.) *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (suggesting that in an infringement action under 35 U.S.C. § 271(e)(2), evidence obtained through discovery may contradict information provided in an ANDA).

3. The Magistrate Judge Erroneously Concluded That Warner-Lambert "Gave Up" When It Realized It Could Not Sustain Its Infringement Claim.

At the close of discovery, TorPharm moved for summary judgment on the '476 patent claim. Warner-Lambert did not oppose the motion, saying in its response that "Warner-Lambert has not been permitted full, compulsory discovery from Teva Israel and has received essentially no factual information concerning the details of the processes by which [TorPharm's] gabapentin is made." (Pl.'s Response to Def.'s Motion for Summ. J. on First Patent Claim at 2.) Warner-Lambert also stated that "[i]nsofar as the summary judgment motion is based on facts that Warner-Lambert was

⁹ A court has discretion to manage the discovery process and "make any order which justice requires to protect a person from annoyance, embarrassment, oppression or undue burden or expense" during the discovery process. Fed. R. Civ. P. 26(c). *See also Adamas v. Ameritech Servs., Inc.* 231 F.3d 414, 432 (7th Cir. 2000) (district courts have great authority and discretion over discovery matters). We allowed the discovery process to continue until October 3, 2000. TorPharm filed its motion for summary judgment shortly thereafter.

permitted to discover, Warner-Lambert does not oppose it – in fact, Warner-Lambert has repeatedly made clear it would not.” (*Id.*)

In his R&R, Magistrate Judge Keys found that Warner-Lambert’s “giving up” at this stage “undermine[s] [TorPharm’s] allegation of bad faith on Warner-Lambert’s part.” (R&R at 12.) TorPharm’s objection to this part of the R&R is really a continuation of its earlier objections, essentially saying that Warner-Lambert should not have waited so long before admitting defeat on this claim. We disagree with TorPharm and believe we have already commented sufficiently on Warner-Lambert’s right to engage in discovery.

4. The Magistrate Judge Improperly Relied on the Purepac Decision to Deny TorPharm’s Motion for Attorneys’ Fees.

The *Purepac* litigation involved essentially the same patent infringement issues that were involved here, but in *Purepac*, Warner-Lambert sued Purepac Pharmaceutical Company (Purepac), another maker of generic gabapentin. *See Warner-Lambert Co. v. Purepac Pharm. Co.*, Nos. 98-2729 and 99-5948, slip op. (D.N.J. May 22, 2003) (memorandum opinion and order on motion for summary judgment and attorneys’ fees under 35 U.S.C. § 285). In that case, Judge Lifland granted Purepac’s motion for summary judgment on the infringement claims of the ‘476 and ‘479 patents, but denied Purepac’s request for attorneys’ fees. Judge Lifland stated that “it would be unjust to punish Warner-Lambert for defending its patent rights, particularly given the high stakes involved in this dispute” and that Warner-Lambert “had the right to investigate [Purepac’s representations that the generic gabapentin was anhydrous and produced in Israel] by engaging in discovery.” *Id.* at 7.

TorPharm asserts that the magistrate judge improperly relied on this decision to deny its motion for attorneys' fees. We do not agree that Magistrate Judge Keys relied on this decision. Magistrate Judge Keys devoted one paragraph of his R&R to the *Purepac* decision and said only that he "could not agree more" with Judge Lifland comments regarding Warner-Lambert's right to engage in discovery. (R&R at 12-13.) It is clear from the R&R that the magistrate judge examined the evidence presented *in this case* and came to his conclusion based on that evidence. His reference to Judge Lifland's comments is nothing more than an expression of agreement with the position that it is reasonable for a patent holder to engage in discovery to investigate representations made in an ANDA. We do not disagree with this position. *See Abbott Labs.*, 300 F.3d at 1373 (an infringement action under section 271(e)(2) takes all relevant evidence into account and some of this evidence may contradict information provided in an ANDA).

B. The '479 Patent

1. *The Magistrate Judge Improperly Assumed That the Issue Addressed by the Federal Circuit Resolved TorPharm's Motion for Attorneys' Fees.*

The '479 patent infringement claim involved the following: the '479 patent claims a method of using gabapentin in the treatment of neurodegenerative disease, a non FDA-approved use of the drug. TorPharm's ANDA sought approval to use generic gabapentin in the treatment of epilepsy, an off-patent and FDA-approved use. Thus, asserted TorPharm, the '479 patent would not be infringed by TorPharm's product. Warner-Lambert argued that, as is typical for the industry, once a generic version of its Neurontin® drug becomes available, doctors will prescribe the generic drug for all uses where Neurontin® is used, even off-label, or non FDA-approved uses, such as in the

treatment of neurodegenerative diseases (the use covered by Warner-Lambert's '479 patent). In filing the ANDA seeking FDA approval to market generic gabapentin in the treatment of epilepsy, TorPharm knowingly would cause the drug to be used (by doctors writing prescriptions and pharmacists substituting generics) for the patented neurodegenerative uses. (Compl. ¶¶ 22, 23).

TorPharm moved for summary judgment on this claim early on in the case, and we denied its motion. In our Opinion, we stated that an inducement of infringement theory (which typically involves an *existing* manufacture, use or sale of an infringing product) can be used to support a suit brought under 35 U.S.C. § 271(e)(2) (which involves the filing of an ANDA and possible infringement *in anticipation of* the manufacture, use or sale of a particular drug), regardless of whether the '479 patent claimed the use covered by the ANDA. *See Warner-Lambert Co. v. Apotex Corp.*, 1999 WL 259946, at *2-3 (N.D. Ill. Apr. 8, 1999). After the close of discovery, TorPharm filed a second motion for summary judgment, which we granted. We found that Warner-Lambert produced no evidence that "[TorPharm] actively encouraged doctors to prescribe their product for neurodegenerative diseases" or that TorPharm "knew doctors were prescribing gabapentin for the neurodegenerative diseases covered by the '479 patent." *Warner-Lambert Co. v. Apotex Corp.*, 2001 WL 1104618, at *3 (N.D. Ill. Sept. 14, 2001). Warner-Lambert appealed to the Federal Circuit.

On appeal, the Federal Circuit held that "it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-55 (Fed. Cir. 2003). The court reasoned that "because an ANDA may not seek approval for an off-label use of a drug . . . it necessarily follows that 35 U.S.C. § 271

(e)(2)(A) does not apply to a use patent claiming only such use.” *Id.* at 1356. The court affirmed our decision granting summary judgment to TorPharm.

In addition, the court determined that Warner-Lambert could have succeeded if it could have demonstrated “the existence of a genuine issue of material fact to support a traditional infringement claim, *i.e.*, that [TorPharm] induced or will induce infringement of the neurodegenerative method patent.” *Id.* at 1356. The court then considered the standard inducement of infringement theory under 35 U.S.C. § 271(b), anticipating that the issue may arise if the ANDA is approved. The court found against Warner-Lambert. *Id.* at 1363-66.

TorPharm maintains that the issue in this case was not one of statutory interpretation of section 271(e)(2) but rather was always one of inducement of infringement under section 271(b), and Warner-Lambert knew that, given the facts of this case, TorPharm could not be liable for inducement of infringement.¹⁰

We do not adopt TorPharm’s position on this matter. It is clear that this suit involved a claim under section 271(e)(2) as well as under traditional inducement of infringement theory and that the claim had a reasonable basis in law and in fact. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d at 1353 n.2, 1356; *Warner-Lambert Co. v. Apotex Corp.*, 1999 WL 259946, at *2-3; Compl. ¶ 22. The suit involved novel issues of statutory construction. *See Warner-Lambert Co.*, 316 F.3d at 1354 (“[t]he central issue in the present case . . . presents a matter of first impression for this court”). The Federal Circuit ultimately decided the issue in TorPharm’s favor, but, as Magistrate Judge Keys

¹⁰ To be liable under an inducement of infringement theory, one must show that the defendant “induced infringing acts and that he knew or should have known its actions would induce actual infringements.” *Manville Sales Corp. v. Paramount Sys., Inc.* 917 F.2d 544, 553 (Fed. Cir. 1990). The facts showed that TorPharm does not market its products directly to doctors or pharmacists and that doctors learn about off-label uses for drugs from professional meetings and conferences, medical literature and studies, and not from drug companies. *Warner-Lambert Co. v. Apotex Corp.*, 2001 WL 1104618, at *3 (facts deemed admitted for purposes of summary judgment motion).

pointed out, a subsequent decision from that court suggests that a decision in TorPharm's favor was not so predictable. *See Allergan, Inc. v. Alcon Labs. Inc.*, 324 F.3d 1322, 1334-35 (Fed. Cir. 2003), *cert. denied*, 2003 WL22231606 (Dec. 1, 2003). Regardless, a case is not considered frivolous simply because a litigant is not successful on the merits. Moreover, in denying TorPharm's first motion for summary judgment, we found that a genuine issue of material fact existed as to the inducement question. Based on the record, we do not find this case exceptional under 35 U.S.C. § 285. TorPharm has not shown by clear and convincing evidence that Warner-Lambert's position on the '479 patent throughout the suit was untenable.

Because TorPharm has failed to show by clear and convincing evidence that Warner-Lambert's claim on either issue was frivolous either at the case's inception or throughout its duration, this case is not exceptional under 35 U.S.C. § 285 and we decline to award attorneys' fees thereunder.

C. Sanctions Under Rule 11

TorPharm asserts that the same rationale that applies to its argument for attorneys' fees under 35 U.S.C. § 285 supports its argument for the award of attorneys' fees as sanctions under Rule 11. For the reasons already articulated above, we adopt the Magistrate Judge's R&R on this issue and deny TorPharm's motion for sanctions under Rule 11.

III. Conclusion

For the foregoing reasons, the Court accepts the magistrate judge's R&R and denies TorPharm's motion for attorneys' fees under both 35 U.S.C. § 285 and Rule 11. We award TorPharm costs in the amount of \$20,876.53.

ENTER:



UNITED STATES DISTRICT JUDGE

DATED: December 3, 2003